

**Amendments to the Drawings**

In accordance with 37 CFR § 1.121(d)(1), attached hereto are five annotated sheets depicting changes made to drawing Figures 1-8. While Applicant acknowledges that the drawings filed on July 13, 2005, have been accepted by the examiner, the attached Figures 1-8 have been amended for improved clarity to better comply with 37 CFR § 1.84(1).

Also attached hereto are five replacement sheets of drawings, incorporating the changes made to Figures 1-8, which replace the drawing figures originally submitted with the application.

**Remarks**

Reconsideration and allowance of this application, as amended, are respectfully requested.

Applicant first hereby affirms the telephonic election of Group I, claims 1-11, made with traverse on November 2, 2006, in response to the restriction requirement imposed on the same date.

In the present Amendment, the written description portion of the specification, the abstract of the disclosure, drawing Figures 1-8, and claims 1-11 have been amended. New claims 16-20 have been added. Claims 1-20 are now pending in the application, with claims 12-15 withdrawn from consideration as being directed to a non-elected invention. Claims 1 and 18 are independent. The objections and rejections are respectfully submitted to be obviated in view of the amendments and remarks presented herein. No new matter has been introduced through the foregoing amendments.

Applicant acknowledges with gratitude the indication of allowable subject matter in dependent claims 5-9 and 11.

The specification has been editorially amended for conformance with 37 CFR § 1.77(c), for consistency, and to correct any informalities. The abstract has been editorially amended for conformance with 37 CFR § 1.72(b). The drawing figures have been amended as described above in the "Amendments to the Drawings" section. Claims 4 and 10<sup>1</sup> have been amended to overcome the examiner's objections. Claims 1-11 have been amended to more fully

comply with U.S. practice. New claims 16-20 have been added to further define the scope of protection sought for Applicant's invention.

Entry of each of the amendments is respectfully requested.

35 U.S.C. § 103(a) - Rochat and Macabasco

Claims 1, 2, and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,269,924 to Rochat in view of U.S. Patent No. 5,573,527 to Macabasco et al. (hereinafter "Macabasco").

The Office Action asserts that "[w]ith respect to claims 1 and 2 Rochat discloses a blood collecting and filtering apparatus 10 comprising two outer sheets and a third inner, flexible, screen-like sheet 12, which divides the bag into a first chamber 13 and second 14 chamber (see Figure 1), and a circular bushing 21 which is in communication with a first opening 15 of the bushing 21 to enable connection of the first chamber to a solvent line and a second opening 16 of the bushing 21 to enable exit of solution from the second chamber (see arrows on Figure 1). The Office Action acknowledges that "Rochat, however, does not disclose that the bushing is affixed on the side wall of the bag via a first bore in the outer sheet and a second bore in the inner sheet." The Office Action asserts that "Macabasco et al. disclose a medical bag

comprising a bushing 114 built directly into the side of the bag 102." The Office Action concludes that "[i]t would have been obvious . . . to modify the blood collecting and filtering apparatus with the bushing location of Macabasco et al. in order to remove filtered fluid from a different location on the bag."

The rejection of claims 1, 2, and 10 under § 103(a) based on Rochat and Macabasco is respectfully traversed. The combined disclosures of Rochat and Macabasco would not have rendered obvious Applicant's claimed invention.

By way of review, Applicant's claimed invention (claim 1) is directed to a bicompartiment bag that is adapted to prepare a liquid solution from a powdered solute. As disclosed at specification page 2, lines 22-26 (as amended herein), Applicant's invention

provides a new, extremely simple constructive procedure, to make it suitable to optimally attain its objects, including providing a means to divide the container into two separate chambers, in one of which the powdered product to be converted into a concentrate used in haemodialysis is to be stored.

One feature of Applicant's bicompartiment bag is that it facilitates mixing of the powdered solute and a solvent with a construction that is simpler than that of prior art devices. That is, as disclosed at specification page 4, lines 25-31 (as amended herein)

[t]his embodiment, apart from the remarkable simplification of the bag structure, which makes its construction considerably simpler, divides the interior of the bag into two chambers, one of which is filled with the powdered bicarbonate through which the diluting water must circulate; it succeeds in eliminating the filter with its tubing, which is replaced by a simple membrane which has a screen configuration at the required position and which may have the contour of a stripe.

Another feature of Applicant's bag is that it has a construction that facilitates testing of the structural integrity of each bag prior to use. As disclosed at specification page 5, lines 5-13 (as amended herein):

The construction provides for verification of the watertightness of each unit prior to its filling with the powdered saline material, with the additional advantage that it favours the operation, thus achieving a good heat sealing of the contour due to the fact that the possibility of it being altered by the presence of the salt granules or particles which would later cause leaks is avoided, and it avoids the blockage problem for the suction of the dilution due to the drop caused by the machine pump suction, which could bind or attach the laminar layers comprising the solution suction chamber together.

Accordingly, Applicant's claim 1 defines a bag that includes:

two strong flexible outer sheets and a flexible inner sheet that divides an interior of the bag into a first chamber and a second chamber and that has a screen portion located at a distal end thereof at a bottom portion of the bag, the two outer sheets and the inner sheet being watertightly joined at a periphery thereof, one of the two outer sheets having a first aperture located therein and an access bushing disposed in the first aperture, the inner sheet having a second aperture located therein that is in communication with the bushing and the inner sheet being affixed at a

periphery of the second aperture to a plane of a bushing end that projects into the bag, the bushing having a first opening therein that provides communication between a solvent inlet line and the first chamber, and the bushing having a second opening therein that provides communication between the second chamber and a solution discharge line.

The combined disclosures of Rochat and Macabasco do not teach all of Applicant's claim features. In Rochat's "Blood Collecting and Filtering Apparatus," blood that enters a first chamber must pass a filter layer before it can be withdrawn from a second chamber. As acknowledged by the examiner, Rochat's bag does not have a bushing that is affixed *on the side wall* of the bag via *a first aperture* in an outer sheet and *a second aperture* in the inner sheet. Instead, in Rochat's device, the two chambers are accessed via two *separate* tubing lines 15 and 16 that are joined to the bag by welding them between the two side walls of the bag. Rochat's construction is suitable for use of a bag in a container 1 having a removably fixed cover 2 (see Figure 1 of Rochat). That, however, is not Applicant's claimed invention.

The disclosure of Macabasco's "Dockable Bag System" does not rectify the above-described deficiencies of Rochat. Macabasco discloses a device for the sterile docking of two or more plastic bags. A pouch 102 contains a bag unit 110 and a predetermined amount of sterile tubing 108 for *connecting* the bag with other bags outside the pouch 102. This sterile tubing 108 has no opening toward the interior of the pouch 102, i.e., "[t]he bag 110 of the

illustrated system may include a port 112, attached to the bag 110, that has an attached amount of tubing 108 that extends from the contents of the bag 110 to outside the system 100" (Macabasco column 3, lines 42-45). An advantage of Macabasco's bag-in-bag arrangement is that the outer bag can enhance the blocking of vapor transmission. But, the combined disclosures of Rochat and Macabasco do not teach all of Applicant's claim features.

Additionally, there is simply no teaching in either Rochat or Macabasco that would have led one to select the references and combine them, let alone in a way that would produce Applicant's claimed invention. Rochat and Macabasco address different technical problems. In solving these problems, Rochat and Macabasco find solutions that are incompatible with one another. That is, Rochat requires a bicompartement bag made of three layers, and Macabasco requires a bag-in-bag arrangement.

Furthermore, even if one were to combine the teachings of Rochat and Macabasco, the result would not be Applicant's claimed bicompartement bag. Taking the teaching of Macabasco, the person skilled in the art might use two separate bushings - one for each pipe in Rochat - for joining the chambers with the pipes. But, that is not Applicant's claimed invention.

There is, therefore, simply no teaching in either Rochat or Macabasco that would have led one to select the references and combine them, let alone in a way that would produce Applicant's

claimed invention. Claims 2 and 10 are allowable because they depend from claim 1, and because they each include an additional feature not taught by either Rochat or Macabasco.

For at least the above reasons, reconsideration and withdrawal of the rejection of claims 1, 2, and 10 under § 103(a) based on Rochat and Macabasco are respectfully requested.

35 U.S.C. § 103(a) – Rochat, Macabasco, and Mathieu

Claims 3 and 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rochat in view of Macabasco, and further in view of U.S. Patent No. 5,616,305 to Mathieu.

The Office Action acknowledges that "Rochat and Macabasco et al., however, do not disclose that the first chamber is at least partially filled with a powdered solute." The Office Action asserts that "Mathieu discloses a hemodialysis packaging unit comprising a layer of sodium bicarbonate powder 74 (column 9, lines 47-55)." The Office Action concludes that "[i]t would have been obvious . . . to modify the blood bag system of Rochat and Macabasco et al. with the layer of sodium bicarbonate of Mathieu in order to allow for dialysis treatment of the blood" and that "in the blood bag system disclosed by Rochat, it is inherent that the layer of sodium bicarbonate would be located in the first chamber 13, before the filtering layer 18, in order to prevent particles from mixing into the blood."



The rejection of claims 3 and 4 under § 103(a) based on Rochat and Macabasco in view of Mathieu is respectfully traversed. The combined disclosures of Rochat, Macabasco, and Mathieu would not have rendered obvious Applicant's claimed invention.

Regardless of what Mathieu may disclose with regard to providing a layer of sodium bicarbonate powder, the disclosure of Mathieu does not rectify any of the above-described deficiencies of Rochat and Macabasco associated with the structural features of the bag. Thus, the combined disclosures of Rochat, Macabasco, and Mathieu do not teach all of Applicant's claim features.

Furthermore, there is no teaching in any of Rochat, Macabasco, and Mathieu that would have led one to select the references and combine them in a way that would produce the invention defined by any of Applicant's pending claims.

For at least the above reasons, reconsideration and withdrawal of the rejection of claims 3 and 4 under § 103(a) based on Rochat, Macabasco, and Mathieu are respectfully requested.


New claims 16-20 have been added to further define the scope of protection sought for Applicant's invention. New claims 16-20 are also allowable. Since independent claim 18 includes at least the features discussed above with respect to the rejections over the applied prior art, the references neither anticipate nor would have rendered obvious the bicompartiment bag defined by new claims 16-20.

U.S. Appln. No.: 10/542,144  
Atty. Docket No.: P70596US0

In view of the foregoing, this application is now in condition for allowance. If the examiner believes that an interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

JACOBSON HOLMAN PLLC

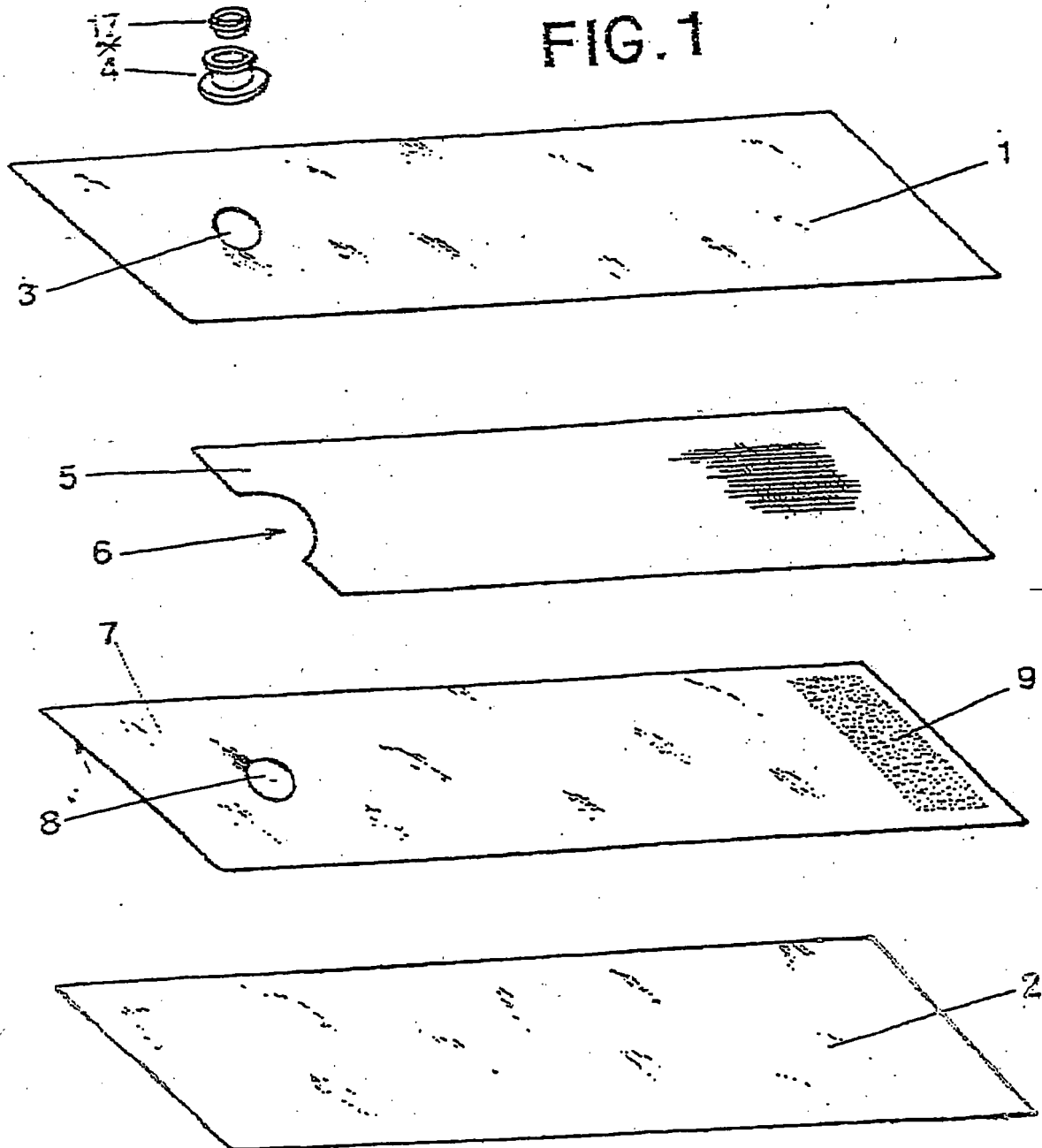
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Date: April 23, 2007



Annotated Sheet

FIG. 1





Annotated Sheet

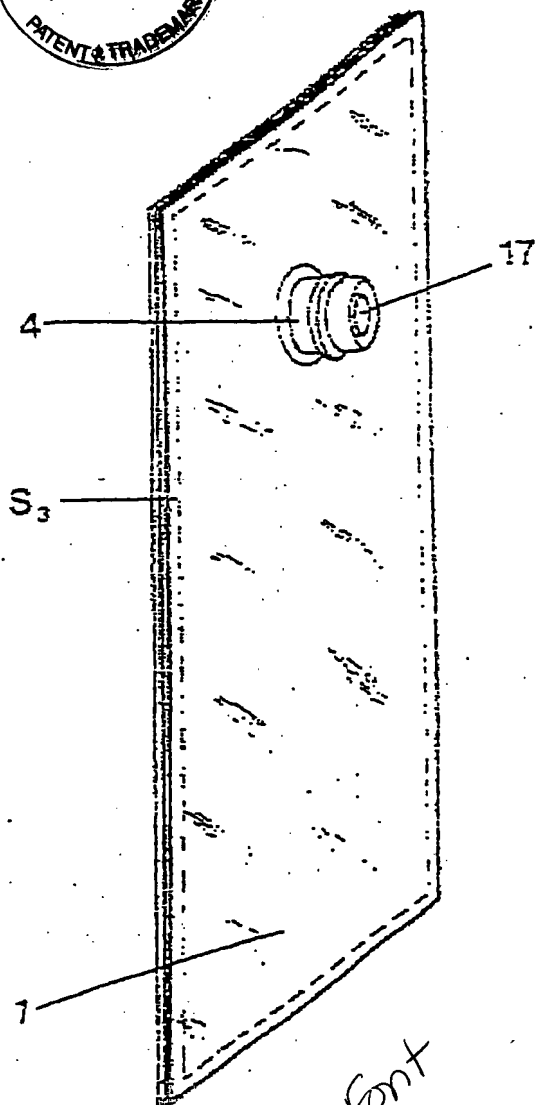
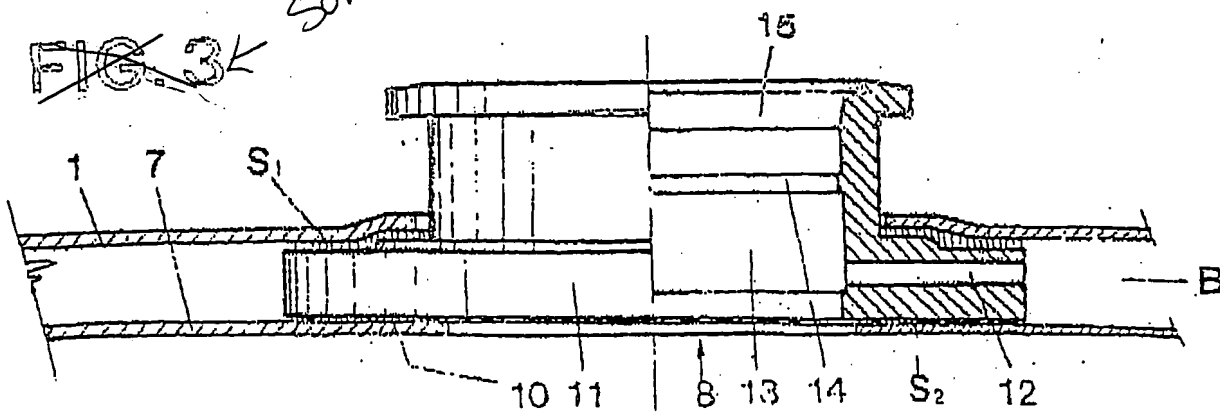


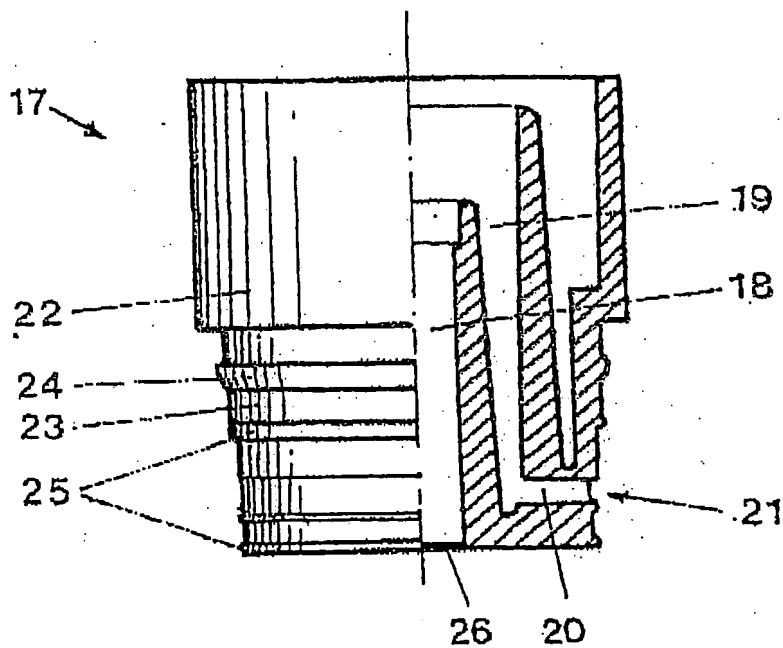
FIG. 2

~~FIG. 3~~ Solid Font

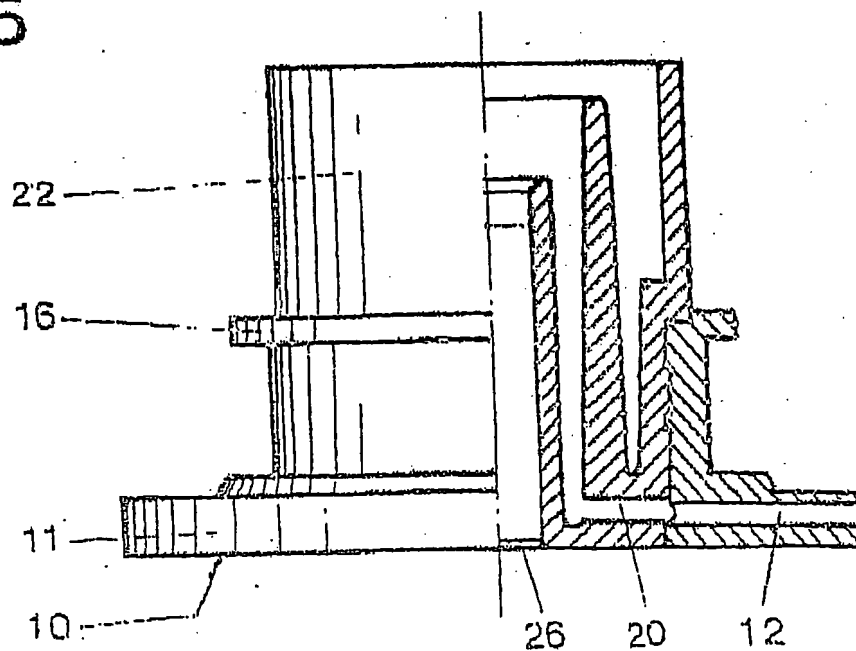




**FIG.4**



**FIG.5**



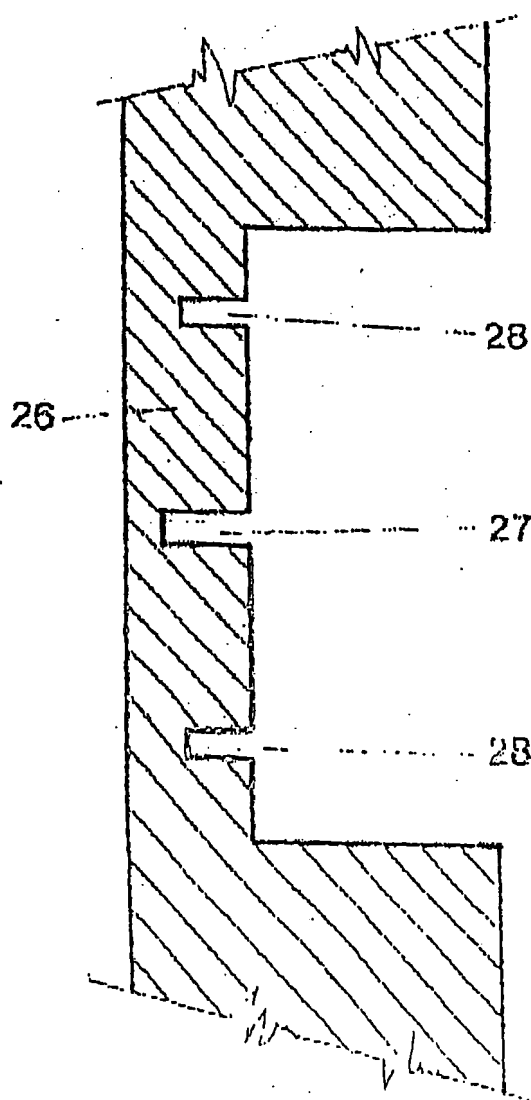
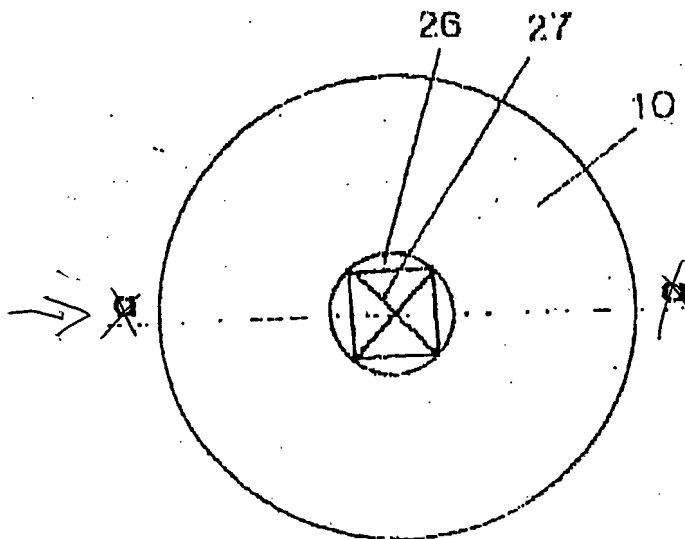
*Clean-up*



Annotated Sheet

**FIG. 6**

*Clean-up*



**FIG. 7**



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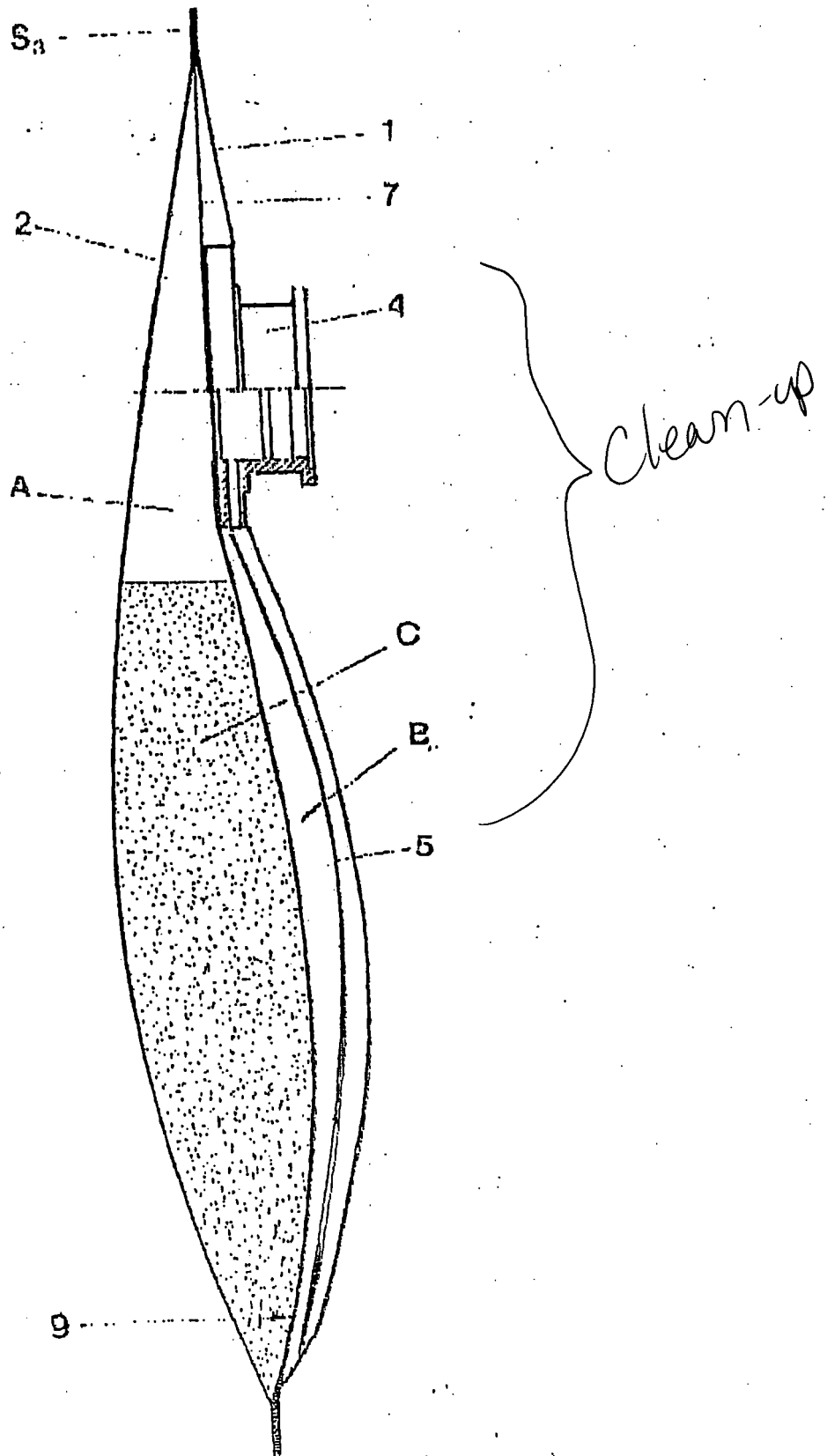


FIG. 8